HUMCO CALAGESIC- calamine and pramoxine hydrochloride lotion Humco Holding Group, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Private Label Calagesic Lotion

Drug Facts

Active Ingredients

Calamine 8%

Pramoxine HCl 1%

Purpose

Skin Protectant

External analgesic

Uses

Dries the oozing and weeping, and temporarily relieves pain and itching of poison ivy, oak, and sumac or other skin irritations.

Warnings

For external use only. Use only as directed.

When using this product. Avoid contact with eyes and moucous membranes.

Stop ue and ask a doctor if

condition worsens. Symptoms last for more than 7days or clear up and occur again whitin a few days.

Keep out of reach of children.

In case of accidental ingestion, seek profesional assistance or contact a Poison Control Center immediately.

Directions

Adults and children 2 yr. of age and older. Shake well before using. Cleanse the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth, not more than 3 to 4 times daily as needed for comfort.

Children under 2 yrs. of age. Consult a doctor before use.

Inactive Ingredients

SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methycelulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben and Purified Water.

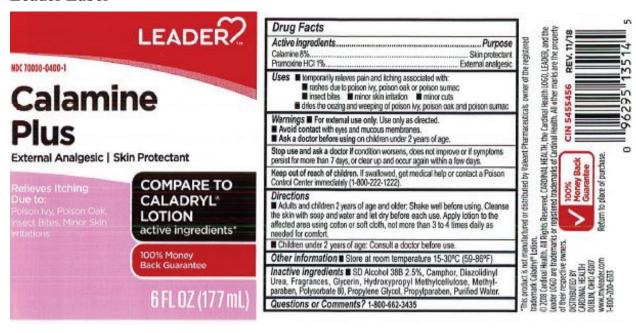
Other information

Store at room temperature 15-30C (59-86F)

Good Neighbor Pharmacy Label



Leader Label



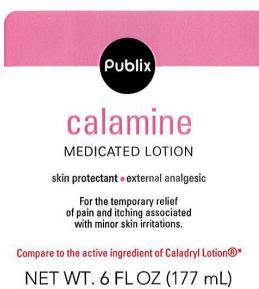
Quality Choice Label



Sunmark Label



Publix Label



Drug Facts

Active ingredients

Skin protectar External analgesi Pramoxine HCI 1%

Use Dries the oozing and weeping, and temporarily relieves pain and itching of poison ivy, oak, and sumac or other minor

Warnings For External Use Only. Use only as directed.

Stop use and ask a doctor if ■ condition worsens ■ symptoms last for more than 7 days or clear up and occur again within a few days. When using this product avoid contact with eyes

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Adults and children 2 yrs. of age and older: Shake well before using. Cleanse the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth not more than 3 to 4 times daily as needed for comfort. Directions

Children under 2 yrs. of age:

Other information Store at room temperature 15° - 30°C

Diazolidinyl Urea, Fragrances, Glycerin, Hypromellose, Methylparaben, Polysorbate 80, Propylene Glycol Inactive ingredients - SD Alcohol 38B 2.5%, Camphor Propylene Propylparaben and Purified Water

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC. 3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811 800-242-1227 • publix.com of the registered trademark Caladryl®.

This poduct is not manufactured or distributed by Pfizer Consumer Healthcare, owne

PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

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Premier Value



CVS Label



Vida Mia Label

Drug Facts

Active ingredients Purpose Calamine 8%.. Skin protectant Pramoxine HCI 1%......External analgesic

Uses Dries the cozing and weeping and temporarily relieves pain and itching of poison ivy, poison oak, and poison sumac or other minor

Warnings

- For external use only. Use only as directed. ■ Avoid contact with eyes and mucous
- Ask a doctor before using on children under 2 years of age.

When using this product discontinue use if condition worsens, does not improve or if symptoms persist for more than 7 days, or clear up and occur again within a few days, and consult a doctor.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center Continued)

This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, owner of the registered trademark Caladryt® Lotion



mi salud Calagesic™ OCIÓN CALAGESIO

External analgesic • Skin protectant

- Drying agent & itch relief Analgésico externo • Protector de la piel
 - Seca y alivia la picazón

6 FL. OZ. (177 mL) • 6 ONZAS FL (177 mL)

Drug Facts (CONTINUED)

Directions

■ Adults and children 2 years of age and older: Shake well before using. Cleanse the skin with soap and water and let dry before each use. Apply lotion to the affected area using cotton or soft cloth, not more than 3 to 4 times daily as needed for

■ Children under 2 years of age: Consult a doctor before use

Other information

Store at room temperature 15-30°C (50-86°F)

Inactive ingredients SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methylcellulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water.

Distributed by/Distribuido por

MAGE LAN

Questions or Comments? @1-800-662-3435

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Información sobre el Medicamento

Ingredientes Activos

Protector de la Pie

Calamina 8%. Pramoxina HCI 1%. ...Analgésico externo

Usos Seca la supuración y el lagrimeo y alivia temporalmente el dolor y la picazón

de la hiedra venenosa, el roble venenoso y el zumaque así como otras irritaciones leves de la pie

Advertencias

- Para uso externo solamente. Utilice únicamente según
- Evite el contacto con los ojos y las membranas
- Consulte un médico antes de usar en niños menores de 2 años de edad.

Al utilizar este producto Suspenda el uso de este producto y consulte un médico si la condición empeora, no mejora o si los sintomas persisten durante más de 7 días o desaparecen y vuelven a ocurrir de nuevo dentro de pocos días.

Mantener fuera del alcance de los niños. En caso de ingestión accidental, busque asistencia profesional o contacte un Centro de Control de Envenenamiento inmediatamente. Continuación >

*Este producto no es fabricado ni distribuido por Johnson & Johnson Consumer Products Company, propietario de la marca registrada Caladryt® Lotion



Caladryl® Lotion*

LOCIÓN CALAGESIC™

Analgésico externo • Protector de la piel

Seca y alivia la picazón



6 ONZAS FL (177 mL)

Información sobre el Medicamento (CONTINUACIÓN)

instrucciones

- Adultos y niños de 2 años de edad o mayores: Agite bien antes de usar, Limpie la piel con agua y jabón y deje secar antes de cada uso. Aplique la loción en el área afectada usando algodón o un paño suave, no más de 3 a 4 veces al día según sea necesario.
- Para niños menores de 2 años de edad: Consulte un médico antes de usar.

Otra información

Almacene a una temperatura de 15-30°C (50-86°F)

Ingredientes inactivos

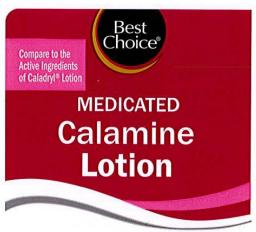
SD Alcohol 38B 2,5%, Alcanfor Diazolidinilurea, Fragancias, Glicerina, Hidroxipropil Metilcelulosa, Metilparabeno, Polisorbato 80, Propilenglicol, Propilparabeno, Agua Purificada.

Distributed by/Distribuido po



Best Choice Label

EDOWN



Topical Analgesic · Skin Protectant · Medicated Pain & Itch Relief Lotion 6 fl oz (177 mL)

Active ingredients Calamine 8%......

Indication Dries the oozing and weeping, and temporarily relieves External analges Pramoxine HCI 1%

Skin protecta

Warnings For External Use Only. Use only as directed pain and itching of poison ivy, poison oak, and poison sumac or othe

Stop use and ask a doctor if ■ condition worsens ■ symptoms last for more than 7 days or clear up and occur again within a few days. When using this product avoid contact with eyes.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control

Adults and children 2 yrs. of age and older: Shake well before using. Cleanse the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth not more than 3 to 4 times daily as needed for comfort.

Other information
Store at room temperature. Children under 2 yrs. of age:

Inactive ingredients ■ SD Alcohol 38B 2.5%, Campho Diazolidinyl Urea, Fragrances, Glycerin, Methylparaben, Polysorbate 80, Prop Propylparaben and Purified Water.

his poduct is not manufactured or distributed by Pfizer Consumer Healtheare, owne of the registered trademark Caladry(®). BEST CHOICE

R041013RLG

HEB Label



Drug Facts

Active ingredients

Purpose Calamine 8%.. Skin protectant Pramoxine 1% External analgesic

Uses Dries the oozing and weeping, and temporarily relieves pain and itching of poison ivy, oak, and sumac or other minor skin irritations.

Warnings: For External Use Only. Use only as directed.

■ Avoid contact with eyes and mucous membranes

■ Ask a doctor before using on children under 2 yrs. of age

When using this product ■ Discontinue use if condition worsens, does not improve or if symptoms persist for more than 7 days, or clear up and occur again within a few days and consult a doctor.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

■ Adults and children 2 yrs. and older: Shake well before using. Wash the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth not more than 3 to 4 times daily as needed for comfort.

Children under 2 yrs. of age: Consult a doctor.

■ Other information ■ Store at room temperature 15° - 30°C (59° - 85°F)

Inactive ingredients ■ SD alcohol 38B 2.5%, camphor, diazolidinyl urea, fragrances, glycerin, hydroxypropyl methylcellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben and purified water.

MADE WITH PRIDE AND CARE FOR H-E-B, SAN ANTONIO, TX 78204 Questions or Comments? Call 1-800-662-3435 1104

We believe the high quality of this H-E-B product makes it an outstanding value. We hope you'll agree. If not, we'll cheerfully refund your money. O





and let dry. Warnings For External Use Only. Use only as directed Stop use and ask a doctor if a condition worsens a symptoms last of children. In case of accidental ingestion assistance or contact a Poison Control SD Alcohol 38B 2.5%, Camphol again within a few days yrs. of age and older: Shake skin with soap and water and let USe Dries the oozing and weeping, and temporarily relibein and itching of polson ivy, oak, and sumac or other n Urea, Fragrances, Glycerin, Hypromell ven, Polysorbate 80, Propylene G using cotton or soft cloth needed for comfort. Store at room temperature. When using this product avoid contact with eyes. up and occur Keep out of reach of childr seek professional assista for more than 7 days or clear Other information Active ingredients before using. Cleanse the Apply to the affected a than 3 to 4 times daily Pramoxine HCI 1% Methylparaben, Drug Facts his poduct is not azolidinyl Calamine

Top care Label

NDC 36800-268-96



COMPARE TO CALADRYL® LOTION ACTIVE INGREDIENT*

Calagesic Lotion

EXTERNAL ANALGESIC SKIN PROTECTANT

Relieves Itching Due to:

- Poison Ivy
- Poison Oak
- Insect Bites
- Minor Skin Irritations



Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center 1-800-222-1222 immediately.

■ Children under 2 years of age: Consult a doctor before use

Other information
Store at room temperature 15-30°C (59-86°F)

Drug Facts

Active ingredients Skin protectant Calamine 8% .External analgesic Pramoxine HCI 1%

Uses: Dries the occing and weeping and temporarily relieves pain and litching of poison by, poison calk, and poison sumac or other minor skin initiations.

Warnings | For external use only. Use only as directed

Avoid contact with eyes and mucous membranes Ask a doctor before using on children under 2 years of age

Stop use and ask a doctor if condition worsens, does not improve or if symptoms persist for more than 7 days, or clear up and occur again within a few days

Directions

Adults and children 2 years of age and older. Shake well before using. Cleanse the skin with scap and water and let dry before each use. Apply lotion to the affected area using cotton or soft cloth, not more than 3 to 4 times daily as

Inactive ingredients SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methylcolfulose, Methyl-peraben, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water

TOPCO ASSOCIATES LLC NEE, IL BONGT GATOPOD BHGA0819 EU-127-98-1-25-0139

stand or distributed owner of the registen

6 FL OZ (177 mL)

HUMCO CALAGESIC

calamine and pramoxine hydrochloride lotion

Product Information HUMAN OTC DRUG Item Code (Source) NDC:0395-9111 Product Type

TOPICAL Route of Administration

Active Ingredient/Active Moiety Basis of Strength Strength Ingredient Name 80 mg ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) ZINC CATION in $1\,mL$ PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB867L5) (PRAMO XINE -**PRAMOXINE** 10 mg HYDROCHLORIDE UNII:068X84E056) in 1 mL

Inactive Ingredients					
Ingredient Name	Strength				
CAMPHOR (NATURAL) (UNII: N20HL7Q941)					
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)					
GLYCERIN (UNII: PDC6A3C0OX)					
METHYLPARABEN (UNII: A2I8 C7HI9 T)					
POLYSORBATE 80 (UNII: 6OZP39ZG8H)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
PROPYLPARABEN (UNII: Z8IX2SC1OH)					
WATER (UNII: 059QF0KO0R)					

ı	Packaging							
	#]	item Code	Package Description	Marketing Start Date	Marketing End Date			
	1 ND 96	C:0395-9111-	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/13/2017				

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part347	03/25/1998					

Labeler - Humco Holding Group, Inc. (825672884)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment				
Name	Address	ID/FEI	Business Operations	
Humco Holding Group, Inc.		825672884	manufacture(0395-9111), analysis(0395-9111), pack(0395-9111), label(0395-9111)	

Revised: 6/2020 Humco Holding Group, Inc.